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No. 88-330

IN THE
Supreme Court of the United States
OCTOBER TERM, 1988

AMERICAN CYANAMID COMPANY,
Petitioner,

v.

TRACY ISABEL ABBOT,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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PETITIONER'S REPLY BRIEF

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PETITIONER'S REPLY BRIEF

ARGUMENT

I. THIS CASE HAS URGENT FEDERAL PUBLIC HEALTH POLICY RAMIFICATIONS

Respondent argues that the 1986 Act precludes finding any implied federal preemption of state law design defect claims because Congress left plaintiffs with the option of rejecting no-fault federal compensation and invoking state tort law to pursue vaccine-related injury claims. This assertion misses the point. While Con-

gress could rationally have concluded that the imposition of damages for conduct such as the defective manufacture or the negligent administration of a vaccine would not frustrate the clear Congressional objective of assuring the continued availability of childhood vaccines, it is most unlikely that Congress would have viewed state tort liability for design defect claims like respondent's in the same light. Such liability, if imposed, would totally remove from the market the only pertussis vaccine which the Department of Health and Human Services now licenses as safe and effective for use. For the reasons set forth in the Petition, the 1986 Act cannot be read as a Congressional attempt to cut back on the pre-existing preemption of such claims. Had Congress intended to allow such claims, it would hardly have legislated the specific limited preemption of such claims contained in the 1986 Act, adopting the Comment k defense of the Restatement (Second) of Torts, § 402A, as a preemptive federal rule of law.[1]

II. THE DECISION BELOW CONFLICTS IN A SIGNIFICANT RESPECT WITH THE FIFTH CIRCUIT'S *HURLEY* DECISION

Respondent asserts that the Fifth Circuit's decision in *Hurley v. Lederle Laboratories*, 851 F.2d 1536 (5th Cir. 1988) (Appendix K to the Petition) "hardly creates a conflict" (Opp. at 4), but she devotes more than a page of footnote argument to trying to explain why no conflict exists. In the end, she is reduced to speculating that the *Hurley* opinion must contain a significant typographical error, and therefore does not mean what its text plainly says. (Opp. at 4-5 n.6).

In *Hurley*, the Fifth Circuit overturned a district court holding that it characterized as "*so broadly phrased* as to preempt all of state products liability law for the

[1] See 42 U.S.C.A. § 300aa-22(b)(1) (West. Supp. 1988).

manufacture and distribution of the pertussis vaccine." [2] The *Hurley* court noted, however, that its rejection of the broad preemption holding "does not exclude the possibility" of a limited preemption of design defect claims.[3] The court then held that the "federal interest in encouraging manufacturers to produce vaccines" [4] supports a limited, implied preemption of *warning* claims where the FDA is apprised of all "necessary and available" information.[5] In light of this holding, it is hardly remarkable that the *Hurley* court would think it "likely" that "a parallel analysis to that applied in the warning context should apply to design defect claims," [6] and there is no basis for respondent's hypothesis that the court meant to say "unlikely" instead of "likely." (Opp. at 5 n.6.)

III. THE DECISION BELOW CONFLICTS WITH THIS COURT'S *BOYLE* DECISION

Respondent argues that in the context of state tort claims for vaccine-related injuries, the rationale of this Court's decision in *Boyle v. United Technologies Corp.*, 108 S. Ct. 2510 (1988), is supplanted by the explicit provisions of the 1986 Act. (Opp. at 8-10.) To the contrary, the *Boyle* preemption analysis dovetails with the limited preemption of the 1986 Act.

The *Boyle* rationale seeks to avoid the circumvention of the Federal Tort Claims Act that would occur by allowing recovery against private manufacturers for injuries resulting from product designs that are effectively mandated and promoted for use by the federal govern-

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[2] 851 F.2d at 1539; Appendix K to the Petition at 63a (emphasis added).

[3] *Id.* at 1543 n.4; Appendix K to the Petition at 70a n.4.

[4] *Id.* at 1543; Appendix K to the Petition at 70a.

[5] *Id.* at 1542; Appendix K to the Petition at 69a-70a.

[6] *Id.* at 1543 n.4; Appendix K to the Petition at 70a n.4.

ment. The limited preemption of the 1986 Act's federal defense seeks to do the same thing by ensuring the availability of needed vaccines that are unavoidably dangerous. Where, as here, the FDA effectively mandates a particular vaccine design—affirmatively rejecting alternatives [7]—it has acted just as the Government contracting officer did in *Boyle*, and, for all practical purposes, it has decreed any risk associated with the vaccine to be unavoidable.[8]

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[7] Contrary to respondent's assertion (Opp. at 9-10), federal regulations do not *require* FDA to license any vaccine that it, in its discretion, views as unsafe or ineffective. FDA may not license any vaccine unless it finds that vaccine to be safe and effective—a finding it now declines to make for alternative pertussis vaccine designs. *See* Petition at 21 n.62.

[8] Respondent suggests that, by including the federal "Comment k" defense as part of the 1986 Act, Congress intended that *juries* decide whether a particular vaccine design was or was not "unavoidably dangerous." That is not what the 1986 Act says, and it is inconsistent with the way many state courts have interpreted state law versions of Comment k. *See, e.g., Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988); *Johnson v. American Cyanamid Co.*, 239 Kan. 279, 718 P.2d 1318 (1986). Here, the vaccine design at issue is the only pertussis vaccine design licensed as safe and effective for use in the United States, and FDA and HHS, the federal licensing authorities, have stated that the whole-cell pertussis vaccine is the only pertussis vaccine design safe enough and effective enough for licensing in the United States. Respondent's reference to an alternative pertussis vaccine marketed by Eli Lilly and Company until 1977 (Opp. at 2, n.2, 10) lacks relevance in light of subsequent research developments that inform FDA's and HHS's current views on vaccine safety and efficacy. *See* HHS *Amicus* Brief, Appendix H to the Petition at 45a-51a & n.8.

Respondent also argues that the "unavoidably dangerous" concept of Comment k to the Restatement (Second) of Torts, § 402A, on which the federal defense in the 1986 Act is modeled, defeats only strict liability claims, and not claims grounded in negligence. (Opp. at 7-8.) As numerous authorities have noted, however, in the context of design defect claims distinctions between strict liability and negligence are not meaningful. *See, e.g.*, W. Prosser, *Law of*

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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Torts, 659 n.72 (4th ed. 1971); Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 841 (1973); *see also Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297, 317-18 (1987) (Bakes, J., specially concurring in part); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374, 385-86 (1984). And, indeed, contrary to respondent's assertion, Comment k *is* sometimes imposed as a complete barrier to any design defect claims involving drugs or vaccines, including negligent design claims. *See Brown v. Superior Court, supra.*